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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,320	08/29/2001	Kamal D. Mehta	D6351	7732

7590

10/24/2003

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/942,320

Applicant(s)
Mehta et al.

Examiner
Maryam Monshipouri

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-3 and newly presented claim 7 are still at issue and are present for examination.

Claims 4-6 are withdrawn and drawn to non-elected subject matter.

Applicants' arguments filed on 8/11/2003 (paper # 7), have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inducing low density lipoprotein (LDL) receptor expression comprising contacting HepG2 cells with TPA or anisomycin, does not reasonably provide enablement for methods of inducing LDL expression comprising contacting **any cell** with a compound that activates p42/44 MAPK, wherein activation of said kinase results in the induction of LDL receptor expression, according to previous office action.

In traversal of this rejection applicant argues that claim 7 has been added to define that the cell of claim 1 is of the HepG2-Raf-1:ER cell line. He/she also agrees with the examiner that the specification is enabling for methods of inducing low density lipoprotein (LDL) receptor expression through contacting said Hep2 cell line with ICI182,780. He/she submits that the

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specification fully enables a person having ordinary skill in the art to make and use the invention recited in claims 1-3 and 7 and subsequently concludes that the rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. This is because applicant has not amended claim 1 and its dependent claims 2-3 to substitute the term “a cell” with said HepG2 cell line. He/she simply added a new claim namely claim 7, that recites said cell line but said claim depends from rejected claim 1. Addition of claim 7, that is allowable, to claimed subject matter does not render the previously rejected claims in condition for allowance because their scope is broader than claim 7. Again, as mentioned previously, the specification fully enables methods of use of Hep2 cell lines and not “a cell” of claims 1-3. Therefore, the rejection directed to claims 1-3 remain, for the reasons provided above, in addition to reasons provided in the previous office action.

Allowable Subject Matter

3. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because a method of inducing low density receptor expression through the sole activation of P42/44MAPK comprising contacting an Hep2-Raf-1:ER cell line with a P42/44 MAPK activator, wherein the activation of said kinase results in induction of LDL receptor expression, and wherein said compound induces growth arrest in said cells is free of prior art. Further, although the methods of inducing LDL receptor expression through the use of P42/44 MAPK activators were known in the prior art said activator compounds were not capable

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of inducing cell growth arrest while inducing LDL receptor expression. Therefore the claimed invention is also non-obvious.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri Ph.D. whose telephone number is (703) 308-1083. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Dr. P. Achutamurthy, can be reached at (703) 308-3804.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER